



Mailed May 20, 2002

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9 Great Valley Parkway  
Malvern PA 19355

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,270,317

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,270,317, which claims the human drug product AVAPRO® (irbesartan), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 194 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 194 days.

The period of extension has been calculated using the Food and Drug Administration (FDA) determination of the length of the regulatory review period published in the Federal Register of November 19, 1998 (63 Fed. Reg. 64268). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,246 - 228) + 370 \\ &= 879 \text{ days}\end{aligned}$$

Since the regulatory review period began April 30, 1993, before the patent issued (December 14, 1993), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From April 30, 1993 to December 14, 1993 is 228 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (January 29, 1998) plus any patent term extension cannot exceed fourteen years. The period of extension calculated above 879 days, would extend the patent from March 20, 2011 (35 U.S.C. § 154) to September 4, 2012, which is beyond the 14 year limit (the approval date is September 30, 1998, thus the 14-year limit is September 30, 2011). The period of extension is thus limited to September 30, 2011, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its expiration date, March 20, 2011, to and including September 30, 2011, or 194 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:


U.S. Patent No.	:	5,270,317
Granted	:	December 14, 1993
Original Expiration Date	:	March 20, 2011
Applicant	:	Claude Bernhart, et al.
Owner of Record	:	Elf Sanofi
Title	:	N-Substituted Heterocyclic Derivatives, Their Preparation and the Pharmaceutical Compositions in Which They Are Present
Classification	:	514/269
Product Trade Name	:	AVAPRO® (irbesartan)
Term Extended	:	194 days
Expiration Date of Extension	:	September 30, 2011

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents  
Box Patent Ext.  
P.O. Box 2327  
Arlington, VA 22202

By FAX: (703) 872-9411  
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

  
Karin L. Tyson  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: David T. Read  
Acting Director Health Assessment Policy Staff, CDER  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852

RE: AVAPRO® (irbesartan)  
FDA Docket No.: 98E-0781